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FACSIMILE COVER LETTER

To: Examiner Quynh-Nhu Vu
Art Unit 3763
Firm: USPTO
Facsimile: 571-273-3228
From: Paul Levy
Date: September 19, 2008
Re: US Patent Appln. No. 10/500,537
Applicant: Yasushi Fuchia, et al.
Title: IONTOPHORESIS ELECTRODE DEVICE
Atty Ref: 930011-2302

Number of Pages: 4
(including cover page)

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PTOL-413A (08-08)

Approved for use through 09/30/2008. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Applicant Initiated Interview Request Form

Application No.: 10/500,537 First Named Applicant: Yasushi Fuchita
 Examiner: Quynh-Nhu Vu Art Unit: 3763 Status of Application: Pending

Tentative Participants:

(1) Examiner Quynh-Nhu Vu (2) Paul A. Levy
 (3) _____ (4) _____

Proposed Date of Interview: September 25, 2008 Proposed Time: 10 AM/PM

Type of Interview Requested:

(1) ☒ Telephonic (2) ☐ Personal (3) ☐ Video Conference

Exhibit To Be Shown or Demonstrated:

☐ YES ☒ NO

If yes, provide brief description: _____

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1) <u>Rej. §102</u>	<u>1-14</u>	<u>6259946 (Higo)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(2) _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(3) _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(4) _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Continuation Sheet Attached

Brief Description of Argument to be Presented:

See attached sheets - Applicant's representative will call the Examiner at 571-272-3228

An interview was conducted on the above-identified application on _____.

NOTE: This form should be completed by applicant and submitted to the examiner in advance of the interview (see MPEP § 713.01).

This application will not be delayed from issue because of applicant's failure to submit a written record of this interview. Therefore, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible.

Applicant/Applicant's Representative Signature

Paul A. Levy

Typed/Printed Name of Applicant or Representative

45,748

Registration Number, if applicable

Examiner/SPE Signature

This collection of information is required by 37 CFR 1.133. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Applicant(s) : Yasushi FUCHITA et al.
Serial No. : 10/500,537
Title: : IONTOPHORESIS ELECTRODE DEVICE
Filed : July 1, 2004
Examiner : Quynh-Nhu Hoang Vu
Art Unit : 3763

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Current Status of Application:

Applicants received a final action mailed 07/02/2008 rejecting claims 1-14 (all of the claims) in response to an amendment filed 01/29/2007.

Topics for interview:

1. Discussion of distinction between Higo reference and present application.

Claim Language:

The contended language (with proposed amendment) for the interview from claim 1:

"a sheet member . . . having a property for allowing said gel to permeate therein,

wherein, when said gel is disposed on said sheet member in the region to receive the gel, the property of the sheet member to allow the gel to permeate therein is sufficient to provide the retention force resulting from the a permeated portion of the gel is sufficient to retain the gel in the region to receive the gel"

Loosely described, the present invention is an iontophoresis device used for introducing the ions of a medicine into the tissues of a patient. The device has an area to receive a gel containing the drug. The area has a sheet member that is permeable to the gel with the drug. When the gel is placed in the area, the gel permeates into the sheet member. The sheet member is permeable enough so the permeation of the gel into the sheet member results in a retention force sufficient to retain the gel in the device. For example, the gel can be retained in the device when the device is inverted. That is, the gel does not fall out. Pub. App. pars. [0023], [0024] and [0026].

The present invention claims a particular composition of the sheet member to have a recited permeability to gel in the area to receive the gel. That is, the "wherein" clause characterizes the permeability property of the sheet member.

The Office Action at page 3 points to Higo, col. 3, lines 7-28, for disclosing the above sheet-member-permeability/gel-retention feature of claim 1. There is no description of the permeability characteristic of the support (2) or electrolyte layer (3b). Certainly there is no

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discussion of a permeability characteristic with respect to the retention of gel containing the drug (6). *Higo*, FIG. 4.

The Office Action asserts support (2) of *Higo* corresponds with the present application sheet member (50). However, the sheet member of the present application has specific characteristics recited in the claim. In particular, the sheet member has a property of being permeable to the gel. Moreover, the permeability of the sheet member to the gel is such that the portion of the gel that permeates into the sheet member creates a sufficient force to retain the gel.

The support (2) of *Higo* is not characterized in terms of permeability or the extent of permeability of the gel containing the drug (6). The material for support (2) of *Higo* is only characterized as "material with excellent workability, flexibility and suitable shape retention and water retention . . . it is only necessary that the material have the effect mentioned above." *Higo*, col. 3, lines 7-21. Certainly, there is no suggestion the support (2) is made of a material chosen to have permeability to a gel (6) sufficient to retain the gel containing the drug when a portion of the gel permeates therein. Any such suggestion would be sheer speculation.

Thus, *Higo* does not disclose that the support (2) has particular properties with respect to the permeability a gel containing a drug to be introduced into the body of a patient.